In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 8, 2020

STEPHANIE ROSCOE, as Representative of the Estate of B.R., deceased,	*	PUBLISHED
	*	No. 11-206V
Petitioner,	*	Special Master Nora Beth Dorsey
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Hepatitis A ("Hep A") Vaccine; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Meningococcal ("Menactra") Vaccine; Human Papillomavirus ("HPV") Vaccine; Streptococcus Pyogenes; Death.
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Kyle Edward Pozza, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

I. INTRODUCTION

On April 4, 2011, Stephanie Roscoe ("petitioner"), as representative of the estate of B.R., deceased, filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that as a result

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

of receiving hepatitis A ("Hep A"), tetanus-diphtheria-acellular pertussis ("Tdap"), meningococcal ("Menactra"), and human papillomavirus ("HPV") vaccines on March 31, 2009, B.R. suffered fever, leg and bodily pain, emotional and mental confusion and anguish, and death. Petition at 1 (ECF No. 1). Respondent argued against compensation, stating that "this case is not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 16).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner provided preponderant evidence that one or more of the vaccines B.R. received caused her to develop a *Streptococcus pyogenes*[3] infection that caused her death, which satisfies her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

II. ISSUES IN AGREEMENT AND IN DISPUTE

The parties agree that B.R.'s death was "most likely caused by a gram-positive bacteria, *Streptococcus pyogenes* [], that resulted in an infection in her hip, which led to septic shock that ultimately caused her death." Resp. Submission, filed Dec. 20, 2019, at 4 (ECF No. 166); accord Petitioner's ("Pet.") Submission, filed Dec. 23, 2019, at 2 (ECF No. 167). They generally agree that there is a factual issue as to whether B.R. had a sore throat prior to her vaccinations, and if so, the medical significance of her sore throat. Resp. Submission at 4; Pet. Submission at 2. This issue will be addressed as part of the causation analysis related to Althen Prong Two.

The issue in dispute is whether petitioner has established by preponderant evidence that B.R.'s vaccinations administered on March 31, 2009 were a substantial factor in causing her death.

III. BACKGROUND

A. Procedural History

This case has a long and complicated procedural history. Petitioner filed her claim on April 4, 2011, and subsequently filed medical records and an expert report. See Petitioner's Exhibits ("Pet. Exs.") 1-6. On November 18, 2011, respondent filed his Rule 4(c) Report, in which he recommended against compensation. Resp. Rept. at 2. Respondent maintained that petitioner failed to provide a "sound and reliable" medical theory that supports the claim that B.R. was injured and died as a result of the vaccinations. Id. at 11.

[3] *Streptococcus pyogenes* is "a ß-hemolytic species [of Streptococcus] that comprises group A of the Lancefield classification and is toxigenic and pyrogenic." Streptococcus Pyogenes, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=108772 (last visited May 27, 2020). Throughout this Ruling, *Streptococcus pyogenes* may be abbreviated as *S. pyogenes* or simply as strep.

On January 5, 2012, petitioner was ordered to file a supplemental expert report to address the issues raised in respondent's Rule 4(c) Report. Order dated Jan. 5, 2012, at 1 (ECF No. 18). Petitioner sought and was granted several extensions of time within which to file the supplemental expert report, which was ultimately filed on January 15, 2013. Supplemental ("Suppl.") Expert Rept., filed Jan. 15, 2013 (ECF No. 26). Respondent filed an expert report on April 10, 2013. Resp. Ex. A. An entitlement hearing was scheduled for November 19 through 21, 2013. Prehearing ("Prehr'g") Order dated May 14, 2013, at 1 (ECF No. 32). During summer 2013, the parties engaged in settlement negotiations, and on August 22, 2013, the case was referred to Special Master Moran for alternate dispute resolution ("ADR") proceedings. Order dated Aug. 22, 2013, at 2 (ECF No. 38). The case did not proceed to hearing but remained in ADR until February 2014, at which time a 15-Week Stipulation Order was entered and an order removing the case from ADR was issued. See 15-Week Stipulation Order dated Feb. 4, 2014 (ECF No. 44); Order dated Feb. 6, 2014 (ECF No. 45).

On July 8, 2014, a status conference was held by the presiding special master to discuss petitioner's counsel's concerns about the stipulation. Order dated July 8, 2014, at 1 (ECF No. 47). Petitioner's counsel reported that petitioner may have received a settlement for B.R.'s injury and death.[4] Id. Petitioner had been instructed not to disclose information about the settlement and the implications on the agreed upon stipulation related to the present claim. Id. Petitioner's counsel was instructed to obtain more information. Id.

On July 18, 2014, petitioner filed a copy of the complaint she filed in the State Court of Dougherty County, State of Georgia, on April 1, 2011, against a number of individually named physicians, their employers, and Phoebe Putney Memorial Hospital ("Phoebe Putney") for medical negligence and the wrongful death of B.R. Response to Court Order, filed July 18, 2014, at 2-20 (ECF No. 49). Petitioner also filed an amended complaint, which included affidavits of Dr. George Jerome Shaw, III and Dr. Robert Mills, setting forth alleged negligent acts committed by the physicians and nursing staff at Phoebe Putney. Id. at 21-36. Neither the complaint or the amended complaint state any allegations based on the vaccines, against the person who administered the vaccines, or the manufactures of the vaccines. Subsequently, discovery depositions from petitioner's Georgia civil case were filed. (ECF Nos. 55, 58-60).

On July 21, 2014, the special master issued an Order to Show Cause why the case should not be dismissed because the petitioner had a pending civil action when she filed her petition in this Court. Order dated Sept. 25, 2014, at 3 (ECF No. 54). The issue was briefed, and the parties agreed that the controlling case was Schumacher v. Secretary of Health & Human Services, 2 F.3d 1128 (Fed. Cir. 1993). Id. (citing Pet. Brief in Support of Mutual Agreed upon Stipulation Approval and Opposition to Dismissal, filed Aug. 22, 2014, at 3-4 (ECF No. 52); Resp. Reply to Pet. Response to the Order to Show Cause and Motion to Strike, filed Sept. 25, 2014, at 4 (ECF

[4] The Vaccine Act provides, "[i]f a plaintiff has pending a civil action for a vaccine-related injury or death, such person may not file a petition under [the Vaccine Act] for such injury or death." § 11(a)(5)(B). It also provides that if "a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death" results in an award of damages "under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under [the Vaccine Act] for such injury or death." § 11(a)(7).

No. 53)). In Schumacher, the Federal Circuit held that the Vaccine Act does not bar a petitioner from filing a vaccine petition when her pending civil action is not against a vaccine manufacturer or vaccine administrator. Id.; Schumacher, 2 F.3d at 1133. Thus, the special master issued an order in which she ruled that the Vaccine Act did not require dismissal of the petition in this Court. Order dated Sept. 25, 2014, at 3. Respondent was given time to review new evidence, particularly the deposition testimony of the physicians who provided care to B.R. as well as the experts who gave testimony in the State Court civil action in Georgia, and to reevaluate his position as to the settlement agreement. Id. at 4. After review of the new evidence, respondent withdrew the settlement offer and wished to proceed with litigation. Order dated Feb. 20, 2015 (ECF No. 62).

The special master then reviewed the evidence, and issued an order providing her impressions of the evidence. See Order dated Mar. 25, 2015, at 2-8 (ECF No. 63). She listed several options for the parties to take: (1) petitioner can provide pathology slides to the respondent's expert for review; (2) the parties can consider revisiting mediation; and (3) if the parties could not informally resolve the case through settlement, they can proceed to a hearing. Id. at 8. The parties did not revisit mediation. Petitioner was ordered to file medical literature, locate or file the culture results for B.R., and exchange the autopsy slides so that experts for both parties could review them. Order dated Mar. 26, 2015, at 1 (ECF No. 64). Petitioner filed a supplemental expert report by Dr. Harry S. Latham, and respondent filed a supplemental expert report by Dr. Sara Vargas. (ECF Nos. 67, 69).

The case was assigned to the undersigned on February 4, 2016, and an entitlement hearing was set for March 15 and 16, 2017. Notice of Reassignment dated Feb. 4, 2016 (ECF No. 77); Prehr'g Order dated Mar. 22, 2016 (ECF No. 81). On January 17, 2017, the undersigned held a status conference to advise the parties that due to the continuing resolution, the Office of Special Masters did not receive its full budgetary allotment for 2017, and therefore, special masters did not have funds to travel for hearings. Order dated Jan. 18, 2017, at 1 (ECF No. 82). Petitioner requested that the hearing be rescheduled once the continuing resolution had ended, and requested that the hearing be held in Albany, Georgia so that petitioner and B.R.'s family could attend. Id. Alternative hearing dates in June and August 2017 were discussed and provided to the parties. Id. The hearing was rescheduled for June 6 and 7, 2017. Prehr'g Order dated Feb. 3, 2017 (ECF No. 84). The parties filed their respective pre-hearing submissions, and additional documents including medical literature.

On June 2, 2017, petitioner's counsel contacted the undersigned to request that the hearing set for June 6 and 7, 2017 be rescheduled due to petitioner's counsel's medical emergency. Order dated June 5, 2017 (ECF No. 100). The entitlement hearing was cancelled and rescheduled for January 8 and 9, 2018. Id.; order dated Sept. 25, 2017 (ECF No. 106). At the pre-hearing status conference on December 19, 2017, counsel for petitioner advised that he required further hospitalization due to his medical condition, and therefore, the hearing was again postponed and rescheduled for May 21 and 22, 2018. Order dated Dec. 19, 2017 (ECF No. 109); order dated Jan. 31, 2018 (ECF No. 113). Petitioner's counsel was asked to consider associating with co-counsel. Order dated Dec. 19, 2017, at 1; order dated Jan. 31, 2018, at 1. Subsequently, the hearing set for May 2018 was cancelled to allow petitioner's counsel to associate counsel. Order dated Feb. 13, 2018 (ECF No. 115).

On June 25, 2018, petitioner filed a motion to substitute counsel for Attorney Richard Gage. Motion to Substitute Attorney, filed June 25, 2018 (ECF No. 121). The motion was granted and a status conference was held on July 12, 2018 with new counsel. Order dated July 13, 2018 (ECF No. 122). Petitioner requested the opportunity to obtain an additional expert, which was granted, and petitioner was ordered to file the expert report by September 11, 2018. Id. at 1-2. The medical records and other exhibits were refiled in proper format. See Pet. Exs. 12-41. A Vaccine Adverse Event Reporting System ("VAERS") report was also filed. Pet. Ex. 42. After several motions for extension of time were requested and granted, petitioner filed the expert report of Dr. Douglas Miller on March 12, 2019. Pet. Ex. 43. Respondent filed his responsive report on July 15, 2019. Resp. Ex. Z.

On December 24, 2019, petitioner filed a motion to amend the case caption to remove the name of Frederick Parks as a petitioner. Motion to Amend Caption, filed Dec. 24, 2019 (ECF No. 168). Letters of Administration dated October 4, 2013, naming Stephanie Michelle Roscoe as Administrator of the estate of B.R., were also filed. Pet. Ex. 45. The motion amending the case caption was granted on January 3, 2020.[5] Order dated Jan. 3, 2020 (ECF No. 171).

An entitlement hearing was finally held on January 8, 2020 in Atlanta, Georgia. The petitioner attended the hearing but did not testify. See Transcript ("Tr.") 3-4. Petitioner's expert, Dr. Miller, and respondent's expert, Dr. Vargas, testified. Tr. 3. After the hearing, respondent requested the opportunity to brief the deposition testimony of physicians who testified in petitioner's civil action, including Dr. Latham, Dr. Mills, Dr. Mark Noel Burns, and Dr. Belise Livingston-Burns, as well as address additional matters that arose during the hearing. Resp. Status Rept., filed Jan. 22, 2020, at 1-2 (ECF No. 175). Respondent's request was granted. Order dated Jan. 22, 2020 (ECF No. 176). Respondent's post-hearing brief was filed on February 24, 2020, and petitioner filed her post-hearing brief on March 9, 2020. Resp. Post-hearing Brief ("Posthr'g Br."), filed Feb. 24, 2020 (ECF No. 181); Pet. Posthr'g Br., filed Mar. 9, 2020 (ECF No. 182).

This matter is now ripe for adjudication.

B. Summary of Relevant Facts

1. Medical Records

B.R. was born on September 4, 1997. Pet. Ex. 14 at 1. Prior to the March 31, 2009 vaccinations, she had no prior significant illnesses, no previous surgeries, and no hospitalizations since birth. Id. She did have the Sickle Cell Trait. Id.

On March 31, 2009, B.R. presented to her pediatrician's office for her 11-year well-child visit. Pet. Ex. 14 at 3. She had no new complaints. Id. Her records show that she had no known drug allergies. Id. She was afebrile, pulse 90 and regular, and respiratory rate 22. Id. She was

[5] For the sake of accuracy and consistency, this Ruling refers to petitioner instead of petitioners throughout, reflecting that Stephanie Roscoe is the current and proper petitioner, although the petition was originally filed by both Frederick Parks and Stephanie Roscoe.

five feet and three inches tall and weighed 149 pounds. Id. Her BMI was 26.39. Id. Urine dip stick analysis was normal and hemoglobin was normal at 11.8. Id. B.R. received the Hep A and HPV vaccines in her upper right arm and the Tdap and Menactra vaccines in her upper left arm. Id. at 4.

On the following day, April 1, 2009, at 5:45 PM, B.R. was admitted to Phoebe Putney Emergency Department ("ED") with complaints of hip pain and fever. Pet. Ex. 14 at 10. Triage assessment performed at 6:00 PM revealed that B.R. had a fever of 102.9°F, pulse of 115 per minute, and pain level of 10/10. Id. She was noted to have been febrile with poor oral intake. Id. B.R.'s pain began at 3:30 AM, and was described as "affecting [her] left iliac crest and pelvis." Id. at 11. A history was obtained from B.R.'s mother, petitioner. Id. B.R. had no history of cough, sore throat, runny nose, or ear pain. Id. Prior to her arrival, she had "been playful and normally active." Id. She did have history of fever for the last few hours, with a maximum temperature of 102 to 103, without chills or sweats. Id. She had no nausea, vomiting, or diarrhea. Id.

A physical examination was performed by Dr. Alfred L. Woodard. Pet. Ex. 14 at 12. B.R.'s neck was supple with "[n]o significant adenopathy." Id. Her throat was clear with no evidence of inflammation. Id. Her tympanic membranes were clear and there were no signs or symptoms of otitis media (i.e. ear infection). Id. There was no anterior or posterior lymphadenopathy. Id. She had unlabored respirations with good breath sounds, and "[n]o audible rales, ronchi [sic], or wheezing." Id. She did not cough or have wheezing during the examination, and she had no respiratory distress. Id. B.R. was "[m]oderately tender to palpation over the left anterior thigh" and her skin was "clear with no lesions or rash." Id. Diagnosis was fever and pediatric viral syndrome. Id. B.R. was given acetaminophen and ibuprofen. Id. Laboratory tests were performed including a complete blood count ("CBC") with differential, urinalysis, and urine culture. Id. at 13. The differential portion of B.R.'s CBC was abnormal, with lymphocytes low at 13.1% (normal 26.0-40.0) and monocytes elevated at 12.6% (normal 1.0-9.0). Id. B.R.'s urinalysis was normal. Id. The results of the urine culture were not reported back before B.R.'s discharge from the ED, but subsequently the report showed less than 100,000 morphotype bacteria with no predominant organism. Id. at 18.

B.R. was discharged from the ED at 8:47 PM by Dr. Woodard. Pet. Ex. 14 at 14. Her temperature at the time of discharge remained abnormal and her mother was advised to follow-up with her pediatrician if B.R.'s symptoms worsened. Id. B.R.'s pain at the time of discharge was 2/10. Id.

At 8:04 AM on April 3, 2009, B.R. was taken by her parents to the Palmyra Medical Center ("Palmyra") Emergency Room ("ER") for fever and pain in the left thigh, with nausea and vomiting, and a rash. Pet. Ex. 14 at 120. An "Emergency Room Patient Sign-in Sheet Patient Information" form was completed and stated that B.R. had a "[h]igh fever since Tues[day]. Extreme upper thigh pain. She had 4 vaccines on Tues[day]. Gagging Dehydrated." Id. at 133. On the form's list of signs and symptoms, B.R. was noted to have fever and fatigue. Id. She did not have a cough, shortness of breath, or close contact with a person who had respiratory symptoms. Id.

An initial assessment was performed at 8:20 AM. Pet. Ex. at 120. B.R. was noted to be in mild distress, with an elevated heart rate of 147 and elevated temperature of 102.7 F. Id. Her pain level was 6/10 and her pain was described as aching. Id. She had no respiratory distress and breath sounds were normal. Id. She was seen by Dr. David L. Kocherla who noted a rash on B.R.'s neck. Pet. Ex. 13 at 17. He ordered blood and urine cultures, urinalysis, other laboratory studies, intravenous fluids, and a portable chest X-ray. Pet. Ex. 14 at 122. The urine culture showed "[m]ixed urogenital flora" with no growth of a significant single organism.[6] Pet. Ex. 13 at 24. The chest X-ray impression was "[n]o evidence of frank pneumonia," but "bronchitis or atypical pneumonia" could not be excluded. Id. at 27. Motrin, Tylenol #3 and Zofran were administered. Pet. Ex. 14 at 121. Dr. Kocherla's diagnosis was post-vaccination reaction. Id. at 139. At 1:00 PM, Dr. Kocherla ordered that B.R. be transferred to Phoebe Putney for admission. Id.

B.R. was transported from Palmyra to Phoebe Putney by ambulance. Pet. Ex. 14 at 35. The ambulance trip report states B.R. "is being transferred . . . for follow up care . . . for a possible allergic reaction to immunizations administered on 03/31/2009," and "[B.R.] [complains of] left hip pain," which she describes "as sharp and non radiating" and "[r]ates pain as 10 on 1-10 scale." Id.

After arrival at Phoebe Putney, B.R. was seen by admitting physician, Dr. Belise Livingston. Pet. Ex. 14 at 27. Dr. Livingston's history of present illness includes the fact that B.R. received vaccinations four days prior to her admission, B.R.'s history of fever and left hip pain, and B.R.'s symptoms progressed to the point that "she began having marked difficulty ambulating." Id. Dr. Livingston noted that B.R. had a history of borderline elevated blood pressure thought to be due to her obesity. Id. at 28. B.R. had no history of cough, wheezing, trouble breathing, or respiratory distress. Id. Dr. Livingston charted, "[t]he patient has had a sore throat off and on for the past week" and "[s]he did have some nausea with the sore throat." Id. Dr. Livingston also included that "[t]he mother does report intermittent red rash that has come and gone for the past 3 days." Id.

Dr. Livingston conducted a physical examination, noting that B.R.'s oropharynx was "mildly injected." Pet. Ex. 14 at 28.[7] No significant adenopathy was present. Id. Respiratory sounds were clear bilaterally. Id. B.R. had tenderness of her left upper thigh and hip and she was unable to ambulate due to pain. Id. Dr. Livingston did not see any rashes or lesions at the time of her exam. Id. Consults were obtained from neurology and orthopedics. Id. at 29. The neurologist, Dr. Alan Little, found no evidence of acute neuropathy. Id. at 29, 31-32. The orthopedist, Dr. Thomas M. Darden, noted that B.R. received four vaccines, and his impression was "transient synovitis secondary to the viral load from the vaccine although cannot completely rule out the possibility of a bacterial sepsis of the joint." Id. at 33. An MRI was ordered to evaluate for infection or septic joint. Id. at 34.

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[6] This report was interpreted as a contaminated specimen and not infection. See Tr. 56; Pet. Ex. 13 at 24.

[7] Dr. Livingston's history and physical examination was dictated on April 3, 2009, at 10:19 PM, and transcribed April 4, 2009, at 10:39 AM. Pet. Ex. 14 at 30.

The preliminary interpretation of the MRI was edematous changes "noted within the muscular surrounding of the left hip compatible with myositis/rhabdomyolysis." Pet. Ex. 14 at 29. An abscess was not seen. Id. Dr. Livingston concluded that B.R.'s labs were "consistent with an acute inflammatory process" suggesting possible infectious myositis. Id. at 29-30. She ordered a rapid strep test, throat culture, and influenza ("flu") testing to rule out "likely causes of infectious arthritis or myositis." Id. at 30. The tests were all negative. Id. at 66, 93. Dr. Livingston noted that the blood culture was still pending. Id. at 30. Dr. Livingston stated that it was not clear whether B.R.'s illness was related to her vaccinations. Id. at 58.

At 11:10 PM, the nursing staff received a call from Palmyra reporting that the blood cultures drawn earlier were positive, showing gram positive cocci in chains. Pet. Ex. 14 at 57, 71. Dr. Livingston, was notified, and an antibiotic, ceftriaxone, was ordered. Id. at 57, 71.

Throughout the early hours of April 4, 2009, B.R. received medication for hip pain. See Pet. Ex. 14 at 71. At 1:25 AM, she was given morphine, at 5:10 AM, she was given Toradol, and at 6:45 AM, she was again given morphine. Id. At 6:45 AM, her left hip was described as swollen, with bruising, and the skin was taunt. Id. At 9:30 AM, B.R. was found unresponsive but breathing. Id. at 61-62. Dr. Livingston arrived and a code was called. Id. at 62. B.R. was taken to the ED for emergent care because the ICU was full. Id. at 62, 81. B.R. progressively worsened and despite lengthy resuscitative efforts, she died at 12:27 PM on April 4, 2009. Id. at 70, 81, 112-13.

A VAERS report was filed on or about April 15, 2009. Pet. Ex. 42. The report contains a summary of information that appears to have been taken from B.R.'s medical records. See id.

On April 21, 2009, the death certificate was signed by Dr. Livingston, identifying necrotizing fasciitis (Group A *Streptococcus*) as the cause of death. Pet. Ex. 12.

2. Autopsies

Two autopsies were performed: the first was performed by Dr. Mark N. Burns, the Medical Director of the Laboratory and Pathologist at Phoebe Putney, and the second by Dr. Harry S. Latham, performed at the family's request. See Pet. Ex. 14 at 83-84; Dr. Latham's Autopsy Report ("Latham Autopsy"), filed June 2, 2017 (ECF No. 98).

a. Autopsy by Dr. Mark N. Burns

Dr. Burns performed the initial autopsy on April 7, 2009. Pet. Ex. 14 at 83. External examination revealed "prominate swelling of the left leg" with induration and discoloration of the left groin extending to the medial thigh and superiorly to the iliac crest. Id. at 83-84. Bullae with serosanguinous fluid were present. Id. at 84. External genitalia was unremarkable and there was "no palpable cervical, axillary, or inguinal lymphadenopathy." Id. at 83.

Internal examination showed edema and hemorrhage, as well as "highly variable numbers of coccal bacteria" in the soft tissues of the left leg and thigh. Pet. Ex. 14 at 83, 87. The pleural (lung) surfaces were normal except some apical fibrous adhesions. Id. at 84. The cause of death

was "necrotizing fasciitis (gram positive cocci) with septic shock." Id. at 83 (emphasis omitted). Tissue samples were taken from skin, lymph nodes, left perineal, groin, inguinal and hip, and spleen and liver. Id. at 87.

b. Autopsy by Dr. Harry S. Latham

Dr. Latham also concluded that necrotizing fasciitis due to gram positive cocci of the left upper leg, hip, and inguinal/groin area with septic shock was the cause of death. Latham Autopsy at 6. He described the external, internal, and microscopic findings relative to the left leg and thigh similarly to those noted by Dr. Burns. See id. at 3, 6. Unlike Dr. Burns, Dr. Latham performed a full autopsy to include all of the abdominal organs and brain. See id. at 4-5. Relevant to the issues here, he described the lungs as "markedly edematous and congested" but did not describe any evidence of pneumonia. Id. at 4. Under pathological diagnosis, Dr. Latham noted,

> Status post history of inoculations one day before onset of clinical symptoms. No distinct point of origin for the introduction of the Group A Beta Hemolytic Streptococcus (Streptococcus Pyogenes) is found. However, wounds as minor as pin pricks, needle punctures, bruises, blisters or abrasions are as serious as traumatic injury or surgical incision and can provide an opportunity for bacteria to enter the body.

Id. at 6 (emphasis omitted).

C. Deposition Testimony

As described above in the procedural history, petitioner filed a civil action against a number of defendants alleging medical malpractice arising out of the medical and nursing care provided to B.R. During the pendency of that action, a number of depositions were taken, which were later filed in this matter. A brief summary of each deposition follows.

1. Stephanie Roscoe

Ms. Roscoe's deposition was taken on October 26, 2011. Resp. Ex. L at 1. She is the petitioner and mother of B.R. At the time of these events, she worked at Ryan's Steakhouse. Id. at 13.

On Tuesday, March 31, 2009, Ms. Roscoe had to work, so Mr. Parks took B.R. to the doctor for her routine appointment and vaccinations. Resp. Ex. L at 14, 87. Prior to that doctor's visit, B.R. had no complaints of pain, and did not have a stuffy nose, cough, sore throat, or fever. Id. at 31-32.

At approximately 3:00 AM the morning after her vaccinations, April 1, 2009, B.R. woke her mother and complained of leg pain. Resp. Ex. L at 36-37. B.R. felt warm. Id. at 38. She did not have a runny nose, cough, or sore throat. Id. at 35, 39. Ms. Roscoe had to work that day. Id. at 39. When she got home from work, B.R. continued to complain of leg pain and her skin

was hot. Id. at 40-41. Ms. Roscoe took B.R. to the Phoebe Putney ED, where B.R. was seen by Dr. Woodard. Id. at 42-43. B.R. did not have a cough, and did not complain of sore throat, ear pain, or chills. Id. at 44. She did have nausea and was limping. Id. at 44-46. Dr. Woodward diagnosed B.R. with a reaction to her vaccinations, and recommended Tylenol or Motrin for the fever. Id. at 47.

The next day, April 2, 2009, Ms. Roscoe worked. Resp. Ex. L at 52. When she got home from work, B.R.'s limp was worse and it was more difficult for her to walk. Id. at 53-54. B.R. did not have any complaints of runny nose or cough. Id. at 54-55. About 6:00 AM the next morning, April 3, 2009, B.R. was really hot, in extreme pain, and unable to walk. Id. at 55-56. Ms. Roscoe took her to Palmyra. Id. at 57. After being seen at Palmyra, B.R. was transferred to Phoebe Putney by ambulance. Id. At Phoebe Putney, B.R. was seen by Dr. Livingston and an orthopedist Dr. Darden, and an MRI was performed. Id. at 59-62.

After B.R. passed away, Ms. Roscoe and Mr. Parks wanted to know what caused B.R.'s death and decided to pay for a full autopsy to be performed. Resp. Ex. L at 67.

In addition to filing her deposition from the civil case, Ms. Roscoe filed an affidavit in which she averred that B.R. did not have a "cough or cold prior to receiving the vaccine shots." Pet. Ex. 37 at ¶ 13.

2. Frederick Parks

Mr. Parks is the father of B.R. He gave his deposition on October 26, 2011. Resp. Ex. K at 1. In April 2009, Mr. Parks worked at W.W. Construction Company, pouring asphalt and concrete for parking lots. Id. at 7.

Prior to B.R.'s vaccinations on March 31, 2009, she did not complain of hip pain, sore throat, headache, pain, cough, or runny nose. Resp. Ex. K at 14.

After receiving the vaccinations, B.R. complained that her arms were a bit sore. Resp. Ex. K at 13, 18. The next day, April 1, 2009, after Ms. Roscoe came home from work, B.R. complained that her leg hurt. Id. at 22. After B.R. was seen at the hospital that day, she had a limp. Id. at 27. On April 2, 2009, B.R. laid in her bed most of the day. Id. at 30. She complained of leg pain. Id. The next day, April 3, 2009, Mr. Parks helped get B.R. in the car so that his wife could take her to the hospital. Id. at 37. Mr. Parks came to see his daughter at the hospital on April 3, and again on the morning of April 4. Id. at 40-42, 62.

3. Dr. Mark N. Burns

Dr. Burns attended the first two years of medical school at the University of South Dakota, then transferred and completed his medical training at Emory University. Resp. Ex. Y at 5. He completed his residency in pathology at Emory, and then began practicing pathology at Phoebe Putney in Albany, Georgia, where he worked until he retired. Id. at 5-6. Dr. Burns is board certified in pathology. Id. at 6. In his capacity at the pathologist at Phoebe Putney, he

worked in concert with the medical examiner or coroner to perform autopsies to determine the cause of death. Id. at 8-9.

Dr. Burns testified that B.R. was the youngest patient with necrotizing fasciitis that he had ever seen. Resp. Ex. Y at 16. After completing his evaluation and autopsy, Dr. Burns was unable to determine the etiology of B.R.'s necrotizing fasciitis. Id. at 16-17.

Dr. Burns defined necrotizing fasciitis as,

> an uncommon infectious process that is rapid and life-threatening and requires rapid surgical and antimicrobial intervention. The most common sites of infection are the lower extremities, including the groin and perineal regions. It's a bacterial infection which is rapidly progressing. There's generally a site of entrance, usually a wound of some sort or a natural occurring defect in one of the natural body barriers, such as the skin or the bowel or the urinary or genital tract. The most common organism identified as Strep pyogenes.

Resp. Ex. Y at 22. In a majority of cases, "there's a clearly apparent site of entry, a wound, or an infectious process and localized infection that is readily apparent as the origin of the process." Id. at 23.

Dr. Burns was not able to identify a site of entry for the bacteria that caused B.R.'s illness. Resp. Ex. Y at 22-23. When asked whether B.R.'s vaccinations had anything to do with her illness, Dr. Burns answered no, that there was "no known scientific connection between such unrelated processes." Id. at 23.

Dr. Burns did not do a full autopsy; he did not examine the brain, lungs, or heart. Resp. Ex. Y at 20. He did examine the perineal area and the external genitalia, which were unremarkable. Id. at 72, 74. Further, there was no inguinal lymphadenopathy. Id. at 72.

4. Dr. Harry S. Latham

Dr. Latham attended medical school at the University of North Carolina, and then began his residency in clinical and anatomical pathology in Palo Alto, California, and finished it at the Medical College of Virginia, in Richmond, Virginia. Resp. Ex. J. at 6. He started his practice in Burlington, North Carolina, and then moved to Union and Gaffney, South Carolina. Id. at 7-8. He later moved to Cordele, Georgia, where he worked at Crisp Regional Medical Center. Id. at 8. He has performed approximately 1,600 autopsies over his 40-year career. Id. at 11-12.

Dr. Latham testified that "there was a very good likelihood that the vaccinations may have been the cause" of B.R.'s infection, "[a]nd that was strictly because of time and effect of the event." Resp. Ex. J. at 28. He explained that the cause of necrotizing fasciitis is not always known, "[i]t can be just a small prick and the bacteria get into the body." Id. at 28-29. Dr. Latham expounded on his opinions as follows:

> The reason I thought it might have been the inoculations is simply because she got the inoculations the morning or maybe afternoon of the 31st of March and, within 12 hours or so, she was complaining of pain in her hip. And while it's possible she got an injury somewhere else that introduced the organisms into her body, likelihood, to me, is that it could have been from the inoculations because either sterility wasn't obtained before they did the injection[s] and it was introduced—because we have bacteria all over our body, including beta Strep. And it just resides there. Normally it doesn't cause problems. But if it gets introduced into a certain area where it can grow well, that's when the problems occur.

Id. at 29.

There was no area seen at autopsy that Dr. Latham was able to identify as a site for the introduction of bacteria and no evidence of injury. Resp. Ex. J. at 30-31. Further, Dr. Latham testified that B.R. did not have strep throat. Id. at 35, 37.

When asked how long B.R. had the infection, Dr. Latham responded that the type of bacteria B.R. had causes symptoms fairly quickly and that the pain she had the day after vaccination was caused by the infection. Resp. Ex. J. at 38-39.

5. Dr. Belise Livingston-Burns

Dr. Livingston-Burns[8] gave a deposition on June 25, 2013. Resp. Ex. W at 1. She attended medical school at the University of Chicago, Pritzker School of Medicine, and did her residency in pediatrics at Emory University School of Medicine. Id. at 7. Dr. Livingston-Burns practiced two years at a National Health Service clinic in Lake City, Florida, then joined the Albany Area Primary Health Care practice. Id. at 8.

Dr. Livingston-Burns recalls that B.R.'s presentation on April 3, 2009, was concerning for Guillain-Barré syndrome ("GBS") following vaccination or viral myositis, due to her difficulty walking, leg weakness, and recent vaccines. Resp. Ex. W at 13-14, 25. Her ultimate diagnosis was necrotizing fasciitis and sepsis. Id. at 15. Necrotizing fasciitis was low on the list of differential diagnoses because B.R. had no open wounds and no history of trauma. Id. at 15-16. Dr. Livingston-Burns documented that there were no wounds or lesions noted on B.R.'s skin. Id. at 59.

Due to concern regarding GBS, Dr. Livingston-Burns consulted Dr. Little, a neurologist. Resp. Ex. W at 31. After consultation, Dr. Little's impression was septic versus inflammatory arthritis of the left hip, and he recommended an orthopedic consult who ordered an MRI. Id. at 33-35. The MRI showed edematous changes in the muscle adjacent to the left hip consistent with myositis/rhabdomyolysis with no evidence of abscess. Id. at 38. At that point, Dr. Livingston-Burns ordered an infectious disease consult. Id. at 39. She considered a viral illness, and ordered flu and strep testing, along with other lab studies. Id. at 43-44. The evening of

[8] Dr. Livingston changed her surname to Livingston-Burns sometime between treating B.R. and giving her deposition. See Resp. Ex. W at 5, 7.

April 3, Dr. Livingston-Burns was notified that B.R.'s blood culture was positive for gram-positive cocci in chains, and she suspected some type of Streptococcus, so she ordered antibiotics. Id. at 49-52.

Dr. Livingston-Burns did not offer any opinion as to the source of B.R.'s infection and necrotizing fasciitis. Resp. Ex. W at 124. She believed that a report was filed regarding the B.R.'s vaccinations and the problems she had afterward, but she was not involved in that process. Id. at 125-26.

6. Dr. David Kocherla

Dr. Kocherla's deposition was taken on September 5, 2012. Resp. Ex. X at 1. Dr. Kocherla attended medical school in India, and then took specialized training in general surgery, also in India. Id. at 5-6. He practiced general surgery in India and Iran, and then in 1994 came to the United States, where he completed a three year residency in internal medicine at Long Island Jewish Hospital in New York. Id. at 6-7. After completion of his residency, he moved to Albany, Georgia, where he joined a practice doing internal medicine, family practice, and emergency room care. Id. at 8. Subsequently, he joined Palmyra as a full-time emergency medicine physician. Id. at 9.

Dr. Kocherla provided care to B.R. when she presented to the Palmyra ER on April 3, 2009. Resp. Ex. X at 23-24. Her chief complaints were fever, rash, inability to walk, polymyalgia, and polyarthralgia. Id. at 28-29. She had pain in the left hip, left knee, lower limb myalgia, and lower leg weakness due to pain. Id. at 30. B.R. also had a rash on her neck. Id. at 40, 42. Dr. Kocherla's suspected that B.R. had sepsis and a septic joint due to the tenderness in her left hip and knee and fever. Id. at 37-43. He was aware that she had received four vaccinations four days before, and thought the condition was related to vaccination, and questioned whether she had a rheumatological process. Id. at 42-43. His diagnosis was "post-vaccination reaction," and he ordered a sepsis work up. Id. at 33-34, 37-43.

After Dr. Kocherla reviewed lab results, specifically the elevated sedimentation rate of 57, he thought that B.R. had sepsis or "post-vaccination myopathy." Resp. Ex. X at 53, 56-58. Dr. Kocherla cited UpToDate "[u]nder post-vaccination reactions" as a resource providing information about a vaccination reaction that caused focal pain in the hip and thigh. Id. at 54. After reviewing the lab results, Dr. Kocherla's diagnosis was "unexplained pain in the upper thigh" which could represent myopathy, a rheumatology problem, infection, abscess, sepsis, infected joint, infected tissues, and possibly bone infection. Id. at 58. His working diagnoses were "post-vaccination reaction, polyarthralgia, [and] serum sickness."[9] Id. Because B.R. had a rash, Dr. Kocherla also considered that B.R. might have "Still's Disease or juvenile rheumatoid arthritis," which presents with "rash, fever, and pain in the joints." Id. at 71. He ordered that B.R. be transferred to Dr. Livingston at Phoebe Putney for pediatric care. Id. at 33-34, 49-50.

[9] Serum sickness is "a hypersensitivity reaction to the administration of foreign serum or serum proteins characterized by fever, urticaria, arthralgia, edema, and lymphadenopathy." Serum Sickness, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106046 (last visited May 27, 2020).

7. Dr. Robert W. Mills

Dr. Mills' deposition was taken July 9, 2013. Pet. Ex. 18 at 1. He attended medical school and completed a residency in pediatrics at the Medical College of Ohio. Id. at 13-14. He is in private practice and the Medical Director at Mercy Children's Hospital in Toledo, Ohio. Id. at 18.

Unlike the other physicians who gave a deposition, Dr. Mills did not provide any medical care to B.R.; instead, he was plaintiff's expert in the medical malpractice case. Dr. Mills submitted an expert affidavit, in which he testified that the nurses at Phoebe Putney violated the standard of care by failing to notify a physician on April 4, 2009 of B.R.'s vital signs at 12:00 midnight (BP 76/52, heart rate 140, and respiratory rate 36) and at 4:00 AM (BP 90/48, heart rate 140, and respiratory rate 32). Pet. Ex. 15 at ¶¶ 7(o)-7(r), 10. Dr. Mills' affidavit was required under Georgia law to support a complaint for malpractice against the defendant, Phoebe Putney. Pet. Ex. 18 at 32.

Dr. Mills' deposition testimony generally focused on his opinions as to the nursing care. Pet. Ex. 18 at 58. During his deposition, Dr. Mills was asked whether B.R.'s immunizations played any role in the development of her illness, and he testified that it was "highly, highly unlikely." Id. at 45-46. Dr. Mills stated that since B.R. had the vaccinations in her arm, they were unlikely to seed the infection in her leg. Id. at 46. He explained that in children, infection can seed through mucus membranes, or the nose, throat, or skin. Id. He also testified that little breaks, even tiny breaks in the skin, can seed infection and cause bacteremia. Id. He noted that B.R. had a history of a sore throat, but acknowledged that her strep screen came back negative. Id. at 47. Dr. Mills also questioned whether minor muscle trauma from jogging (described in B.R.'s father's deposition) may have incited the infection, but conceded that opinion was speculative. Id.

D. Affidavits from Family Members and Pastor Mary Whitley

Several affidavits were executed by family members and Pastor Mary Whitley. See Pet. Exs. 33-40. Relevant to the causation issues addressed in this Ruling are statements about B.R.'s health prior to her vaccinations and/or death. Brittany Parks, B.R.'s sister, lived in the same house and shared a bedroom with her sister. Pet. Ex. 38 at ¶ 5. She averred that she "did not observe or witness her sister having any complications with coughs or cold immediately prior to her death." Id. at ¶ 8. Terry Roscoe, B.R.'s brother, similarly testified that "[his] sister never exhibited complications with colds or rash or the like prior to being administered the vaccine shots." Pet. Ex. 39 at ¶ 7. Pastor Whitley testified that prior to the vaccinations, B.R. "never complained about flu or cold or anything of that nature." Pet. Ex. 40 at ¶ 6.

E. Expert Reports

The experts agreed as to the cause of death, necrotizing fasciitis with septic shock due to a bacterial infection caused by *Streptococcus pyogenes*; however, they disagreed as to how B.R. "came to be infected" with the bacteria. Resp. Ex. Z at 1; see also Pet. Ex. 43 at 6-8. Dr. Miller opined that the source of bacteria was B.R.'s vaccinations, whereas Dr. Vargas opined that it

came from the throat, the genital tract, or an unknown origin. Pet. Ex. 43 at 6-8; Resp. Ex. Z at 1-5.

Both experts reviewed the medical records, the autopsy reports, and the autopsy tissue slides. Pet. Ex. 43 at 1; Resp. Ex. A at 1; Resp. Ex. M at 1-2. The medical records do not document redness, warmth, or swelling at B.R.'s vaccination sites. Resp. Ex. A at 7.

1. Petitioner – Dr. Douglas Miller, M.D.

a. Background and Qualifications

Dr. Miller is a physician, certified in both neuropathology and anatomic pathology by the American Board of Pathology. Pet. Ex. 43 at 1. He earned his B.A. from Williams College in Massachusetts in 1974. Pet. Ex. 44 at 1. He then attended University of Miami where he earned both his M.D. and Ph.D. Id. Thereafter, Dr. Miller completed an anatomic pathology residency from 1980 to 1982 and a neuropathology residency from 1982 to 1984 at Massachusetts General Hospital. Id. Since 1984, he has spent his career in academic pathology. Pet. Ex. 43 at 1. Dr. Miller currently works as a Clinical Professor in the Department of Pathology & Anatomical Sciences, Interim Chair of the Department of Pathology & Anatomical Sciences, and the Pathology Residency Director at the University of Missouri School of Medicine. Id. Throughout his career, he has served as a consultant to medical examiners requiring neuropathology subspecialty expertise. Id. at 1-2; Pet. Ex. 44 at 3. Dr. Miller serves on various committees and editorial review boards and has authored or co-authored almost 300 publications. Id. at 4-26.

b. Opinion

i. Althen Prong One

There are two tenets to Dr. Miller's theory of causation. The first tenet is that *Streptococcus pyogenes* is a well-known cause of skin and other infections. Pet. Ex. 43 at 7. This aspect of Dr. Miller's theory is not in dispute.

The second tenet of Dr. Miller's mechanism of causation is that *Streptococcus pyogenes* bacteria can be distributed through the blood stream to various body sites. Tr. 61, 68-69; Pet. Ex. 43 at 7-8. This mode of infection is referred to as hematogenous spread. Tr. 105. Tissue with less perfusion that receives less blood flow, like the fatty area of the thigh, can create a location for infection to set up, particularly in obese persons. Tr. 61. Bacteria grows better in fatty areas than in other body tissue. Id. Dr. Miller opined that a bacterial infection can occur in a site remote from the place where the infection entered the body. Tr. 59-61. Specifically, he testified that in cases of hematogenous spread of bacteria, an infection can occur at a remote site even if there are no symptoms of infection at the site where the bacteria entered the body. Tr. 67-70, 91.

In support of his theory of causation, Dr. Miller cited the Merck Manual, a guidebook for physicians. Tr. 58 (citing Pet. Ex. 26).[10] With regard to necrotizing fasciitis due to *Streptococcus pyogenes*, the Merck Manual states that "[i]noculation originates through the skin or bowel, and the defect may be surgical, trivial, distant from the disease site, or occult, as with colonic diverticula or an appendiceal abscess." Pet. Ex. 26 at 4. Thus, the defect where the bacteria enters the body can be trivial, and Dr. Miller emphasized that the site of bacteria entry may be distant from the disease it causes. Tr. 59-61.

Dr. Miller also referenced an article filed by respondent, authored by Ian F. Cook.[11] Tr. 63-65 (citing Resp. Ex. N). Cook reviewed adverse infectious events that occurred after vaccination, to emphasize the importance of skin disinfection before administering vaccines. Tr. 65. Dr. Miller explained that bacteria can be introduced into the body through the skin via injection, and that is why it is important to sterilize the skin prior to vaccine injection. Tr. 68-69, 85. Even proper disinfection technique does not completely sterilize the skin, and there is some chance for bacteria to be carried through the skin by a needle even if the person who administers the vaccine follows proper procedure. Tr. 86.

Cook reviewed data from a number of sources, including the VAERS database, Vaccine Safety Datalink ("VSD") program, Korean, Italian, and Canadian surveillance programs, Kaiser clinics, Medicare, and published reports in the medical literature. Resp. Ex. N at 2-3. He reported 1534 cases of sepsis[12] following vaccinations, noting that the majority (65.9%) were associated with cellulitis.[13] Id. at 8.

Twelve cases of necrotizing fasciitis were summarized in a Table in the Cook article: seven from the literature and five from the VAERS database. Resp. Ex. N at 6-7 tbl.5. One of the case reports in the table was from a paper authored by Thomas,[14] about an 80-year-old patient who received the flu vaccine in her left upper arm. Id. at 6 tbl.5 (citing Resp. Ex. BB). Two days later, the patient presented with a blue discoloration of her left forearm, "blister-like

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[10] Streptococcal and Enterococcal Infections, Merck Manual, https://www.merckmanuals.com/professional/infectious-diseases/gram-positive-cocci (last visited Sept. 11, 2013).

[11] Ian F. Cook, Sepsis, Parenteral Vaccination and Skin Disinfection, 12 Hum. Vaccines & Immunotherapeutics 2546 (2016).

[12] Cook defined sepsis as a systemic inflammatory response syndrome which occurs when infection is associated with organ dysfunction, hypoperfusion, and/or hypotension. Resp. Ex. N at 8.

[13] Cellulitis is defined as "an acute, infectious and expanding inflammatory condition of the skin." Resp. Ex. N at 2.

[14] M.G. Thomas, *Clostridium Septicum* Gas Gangrene Following Intramuscular Infection from an Influenza Vaccine Booster, 44 British J. Clinical Prac. 709 (1990).

fluid collections" or bullae, and a "cold, pulseless left hand." Tr. 64 (citing Resp. Ex. N at 6 tbl.5). The fluid in the lesions cultured clostridium septicum.[15] Id. (citing Resp. Ex. N at 6 tbl.5). Dr. Miller testified that based on the description provided in Cook, the injection site was the upper left deltoid muscle, and the "subsequent soft tissue infection was in the forearm and hand, without a direct connection to the vaccination site." Tr. 64-65. Dr. Miller noted that the infection was remote from the vaccine site. Tr. 65.

Cook also described ten cases of osteomyelitis[16] following vaccination. Resp. Ex. N at 5. Cook identified three mechanisms of infection spread: haematogenous[17] and contiguous spread with or without vascular insufficiency. Id. One case was due to hematogenous spread[18] after flu vaccination in the right arm of the patient. Id. at 5, 8 tbl.6. The patient's clinical history was notable for cellulitis in the right arm and the patient developed L3-4 vertebral osteomyelitis. Id. at 8 tbl.6. Dr. Miller explained that the mechanism of hematogenous spread of bacteria in the blood stream described in the patient in Cook's article was the same "mode of spread" in B.R.'s case. Tr. 105.

Septic arthritis[19] was another type of adverse infection occurring after vaccination reported by Cook. Resp. Ex. N at 5, 9 tbl.7. Hematogenous spread was reported in four cases of septic arthritis:

1) Male, age 72, had an influenza vaccine given in his left arm. Id. at 9 tbl.7. He developed pain and swelling in his right wrist, arm, and left ankle. Id. Group A strep was cultured from the right wrist. Id.

[15] Clostridium septicum is defined as "a toxicogenic species commonly found in animal intestines and soil, causing diseases such as braxy and malignant edema; in humans it is sometimes associated with gas gangrene." Clostridium Septicum, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=65642 (last visited May 27, 2020).

[16] Osteomyelitis is the "inflammation of bone caused by infection, usually by a pyogenic organism, although any infectious agent may be involved." Osteomyelitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=35862 (last visited May 27, 2020).

[17] This is the British spelling of the word, hematogenous. For clarity, the English spelling will be used throughout this Ruling.

[18] Dr. Miller defined hematogenous as "spread in the bloodstream." Tr. 105.

[19] Septic arthritis is an "infection of the joint." Resp. Ex. N at 5.

2) Female, age 1 year, 1 month, had Hepatitis A and Varicella vaccinations in the left leg, and subsequently was unable to move her left elbow. Id. Aspirate of the left elbow was positive for *Alcaligenes faecalis*.[20] Id.
3) Male, age unknown, had Hepatitis B vaccination in the left leg and developed pain and decreased movement in the left leg, and was diagnosed with septic arthritis of the left hip and ankle. Id. Blood cultures showed methicillin-susceptible *Staphylococcus aureus*[21] ("MSSA"), as did left ankle ulcer. Id.
4) Male, age 16, received the meningococcal and Tdap vaccines in his right arm, and developed methicillin-resistant *Staphylococcus aureus* ("MRSA") bacteremia with left sacroiliac joint, and septic arthritis on bone scan and MRI. Id.

There was no mention of symptoms of infection at the site of vaccination in the four cases described above, where the route of spread was hematogenous. See Resp. Ex. N at 9 tbl.7. Dr. Miller testified that the case involving the 16-year-old male who had a distant site infection illustrates his causal theory. Tr. 110-11.

Dr. Miller also cited another article filed by respondent, authored by Stevens et al.,[22] in support of his opinions. Tr. 65-67 (citing Resp. Ex. Z, Tab 4). The article describes patients who had severe Group A Streptococcal infections. Tr. 66. Dr. Miller notes that "some of the patients did not have any documented portal of entry," explaining that these patients had negative throat cultures and demonstrated no sign of injury to the skin. Tr. 67. Of the patients with no evidence of skin infections, one had a "bacterial infection of the interior of the eye globe" or "endophthalmitis." Id. Dr. Miller opined that the patient with the eye infection had an infection from a source that was "clearly a distant site" and "no detectable site of entry." Id. Therefore, Dr. Miller concluded that the infection had "to be carried in the bloodstream." Id.

ii. Althen Prong Two

The autopsy established that B.R. had *Streptococcus pyogenes*, a bacteria that Dr. Miller opines is known to be present on human skin, and a known cause of human infections. Pet. Ex.

[20] *Alcaligenes faecalis* is "a species isolated from hospital environments and from blood, sputum, and urine specimens." Alcaligenes Faecalis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=55314 (last visited May 27, 2020).

[21] *Staphylococcus aureus* is "a species comprising the yellow-pigmented, coagulase-positive pathogenic forms of [Staphylococcus]" that "causes serious suppurative infections and systemic disease, including impetigo bullosa, staphylococcal pneumonia, and staphylococcal scalded skin syndrome, and has developed resistance to nearly all classes of antibiotics." Staphylococcus Aureus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=108211 (last visited May 27, 2020).

[22] Dennis L. Stevens et al., Severe Group A Streptococcal Infections Associated with a Toxic Shock-like Syndrome and Scarlet Fever Toxin A, 321 New Eng. J. Med. 1 (1989).

43 at 7. Dr. Miller opines that the "autopsy findings are consistent with septic shock from an infection centered in the left hip region." Id. at 4. According to Dr. Miller, bacteria got into the bloodstream at the site of one of B.R.'s vaccinations, and once in the bloodstream, traveled to the thigh, an area of high fat content. Tr. 69. Dr. Miller opines that there was no source of infection other than vaccination as evidenced by the autopsy. Pet. Ex. 43 at 6.

Dr. Miller disagrees with respondent's position that B.R. likely had strep throat, or other infection that caused her necrotizing fasciitis and septic shock. Pet. Ex. 43 at 6. He opines that the clinical history does not provide evidence of any other source or site of infection. Id. At the hearing, Dr. Miller painstakingly reviewed the medical records in chronologic order to support his position that there was no evidence of strep throat that could have been the source of B.R.'s necrotizing fasciitis.[23] See Tr. 13-57.

Dr. Miller began by stating that on March 31, 2009, at B.R.'s well child visit, she had no complaints, her vital signs, lab tests, and urinalysis were normal, and there were no identifiable illnesses. Pet. Ex. 14 at 3-4; Tr. 14. The only issue noted was B.R.'s weight. Tr. 14. Four vaccines were administered at this visit, two in each arm. Pet. Ex. 14 at 4; Tr. 15.

On April 1, 2009, B.R. was seen in the Phoebe Putney ED at 5:45 PM, complaining of hip pain and fever that began that morning at 3:30 AM. Pet. Ex. 14 at 10-12; Tr. 16. B.R. had no infectious disease risk factors, no contacts with illness, had been acting normally, was voiding urine, had no ear pain, had no vomiting or diarrhea, felt hot, and was febrile for two-and-one-half hours. Tr. 17. B.R. denied injury to the hip, and had a fever of 102 to 103. Id.; Pet. Ex. 14 at 11. There was no history of cough, sore throat, stuffy or runny nose, chills, or sweats, and her appetite was okay. Pet. Ex. 14 at 11. A physical exam found B.R. had no ear, nose, or throat abnormalities, her neck was supple, she had no significant adenopathy (no enlarged lymph nodes in her neck, face, or head), and her oropharynx (throat) was clear with no inflammation or evidence of otitis media (ear infection). Id. at 12; Tr. 18-19. She had good breath sounds, no labored breathing, no coughing, and no wheezing. Pet. Ex. 14 at 12; Tr. 19. Lastly, her abdomen was soft with no palpable or enlarged organs, she had good bowel sounds, she had "moderate tenderness to palpation over the left anterior thigh," and her skin was clear with no rash. Tr. 20; see Pet. Ex. 14 at 12.

Based on the clinical history and physical examination on April 1, Dr. Miller concluded there was no evidence that B.R. had strep throat. Tr. 20. Specifically, he testified that she had no inflammation in her throat and no enlarged lymph nodes, which he finds typical for a patient with strep throat. Id. However, Dr. Miller opined that there was evidence that B.R.'s leg was infected on April 1 because she complained of pain and her leg was tender to palpation. Tr. 20-21.

Next, Dr. Miller recounted that B.R. was next seen by a physician on April 3, when she presented to the Palmyra ER with a high fever and "[e]xtreme upper thigh pain." Pet. Ex. 14 at 120, 133; Tr. 21. She was again noted to have no cough, no shortness of breath or difficulty

[23] Dr. Miller's complete review of B.R.'s medical records will not be recounted in this section. For a more detailed summary of relevant facts, see supra Section III.B.1.

breathing, no sore throat, no close contact with anyone who had respiratory symptoms, and no contact with any person having a flu-like illness. Pet. Ex. 14 at 133; Tr. 22. Physical exam revealed B.R. was in mild distress. Pet. Ex. 14 at 120; Tr. 23. She had normal breath sounds, an exam of her head, ears, eyes, nose, and throat was normal, she had no history of trauma, and her skin was warm and intact with no breaks or lesions. Pet. Ex. 14 at 120; Tr. 23-25. Based on the medical records from April 3, Dr. Miller concluded that there was no evidence that B.R. had strep throat. Tr. 26.

Dr. Miller testified that B.R. was transferred from Palmyra to Phoebe Putney later that day and the admitting pediatrician, Dr. Livingston, documented a history and physical exam. Tr. 27-28, 34; see Pet. Ex. 14 at 27-30. On exam, B.R. had no nasal discharge, no cough, no wheezing, and no trouble breathing. Tr. 36. Dr. Livingston stated, "[t]he patient has had a sore throat off and on for the past week" and had "some nausea with the sore throat." Pet. Ex. 14 at 28. B.R. had no pain on urination. Id. She had leg weakness, worse pain in the left hip and thigh, and decreased ambulation. Id. Dr. Livingston also noted that B.R.'s mother reported that B.R. had an "intermittent red rash that had come and gone for the past 3 days." Id. Physical examination revealed B.R.'s oropharynx was "mildly injected," there was "[n]o significant adenopathy," and her lungs were clear. Id. Dr. Miller testified that the phrase "mildly injected" suggests mild irritation or inflammation. Tr. 38. Given the history of vomiting at this point, Dr. Miller stated that the note about B.R. having a sore throat was possibly related to irritated mucus membranes from vomiting, but admitted that without more information, the finding was difficult to interpret. Id.

The next physical exam occurred the morning of April 4, at 9:35 A.M. Tr. 39; see Pet. Ex. 14 at 61. At that time, an exam revealed that B.R. had moist mucus membranes without inflammation, no cough, and clear lungs. Pet. Ex. 14 at 61.

In summary, Dr. Miller testified that B.R. had five consecutive examinations of her throat: March 31, April 1, April 3, evening of April 3, and the morning of April 4. The note on April 3 from Phoebe Putney is the only time that any abnormality is seen and documented, and thus, it is inconsistent with all of the other contemporaneous entries. Tr. 37. Dr. Miller also explained that a child with acute strep throat would have an inflamed throat, often with white follicles and exudate. Tr. 40. Thus, the description by Dr. Livingston on April 3 of "mildly injected" is not consistent with acute strep throat.[24] Id. Further, the rapid strep test and throat culture done on the evening of April 3 were negative. Tr. 32. The throat culture showed no evidence of a strep organism. Id. Dr. Miller testified that the accuracy rate of a rapid strep test combined with a throat culture is 90-95% sensitive. Tr. 32, 71. Thus, he concludes that there is no evidence "at all" that B.R. had strep throat. Tr. 33.

[24] A CDC monograph on Group A Strep and scarlet fever, filed as Respondent's Exhibit Z, Tab 6, describes symptoms of strep throat as very red, sore throat, fever, whitish coating on the tongue, and swollen glands in the neck, consistent with Dr. Miller's testimony on this point. Group A Streptococcal (GAS) Disease, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/groupastrep/diseases-public/scarlet-fever.html (last visited July 13, 2019).

Dr. Miller also disagreed with respondent's suggestion that B.R. had pneumonia or bacterial bronchitis. Pet. Ex. 43 at 6. The lung tissue slides showed "marked congestion and . . . intra-alveolar hemorrhage," as well as "considerable desquamation of alveolar and bronchiolar lining cells and alveolar macrophages, as a terminal and autolytic phenomenon," but there was no pneumonia or indication of a prior infection of the lungs. Id. at 4-5. Dr. Miller disagrees with respondent's expert, Dr. Vargas, that lung tissue slide Q shows "early bronchopneumonia" because Dr. Vargas did not identify any evidence of "early bronchopneumonia" in the other three lung slides. Id. at 5. The areas of lung tissue identified as abnormal by Dr. Vargas are, according to Dr. Miller, artifactual or terminal findings. Id. at 6. Dr. Miller also referred to these findings as "agonal," which are changes that occur during death, and "autolysis," or changes that occur when there is a delay in conducting an autopsy. Tr. 195-96. To the extent that there were any changes consistent with early pneumonia, Dr. Miller opined they would be a consequence of B.R.'s septicemia, and not a preceding infection. Tr. 196. Dr. Miller also notes that B.R.'s records include many statements that her lungs were clear, except a note close in time to her death, where she was noted to be in mild respiratory distress. Id.

Dr. Miller stated that the pathologists who performed the autopsies did not opine that B.R.'s infection started in her throat. Tr. 51-52. B.R.'s urine culture was also negative and not compatible with streptococcus. Tr. 56. Dr. Miller opined that there was no evidence of a urinary tract infection as the course of the infection in B.R.'s medical records. Tr. 70. There was no history of trauma, no other breaks in the skin. Tr. 72. There was no reason for the treating physicians to culture the genital tract as there were no symptoms to suggest that was the source of infection. Tr. 91. Dr. Miller concluded that other than her vaccinations, there is no other explanation as to the cause of B.R.'s infection. Tr. 71.

Dr. Miller agreed that there was no evidence of a local infection at the site of B.R.'s vaccinations. Tr. 91. He pointed out that the Stevens article documented a remote infectious complication (endophthalmitis) from an unknown site of entry. Tr. 89 (citing Resp. Ex. Z, Tab 4). Dr. Miller conceded that in the cases of remote infections cited in Cook, most had an infection at the injection site; however, there were also cases cited in Cook that documented a hematogenous spread of infection, in the same manner that Dr. Miller's asserts occurred in B.R.'s case, where there was no infection described at the site of vaccination. Tr. 89-90, 107-11 (citing Resp. Ex. N at 9 tbl.7).[25]

Consistent with the autopsies, Dr. Miller testified that B.R.'s cause of death was necrotizing fasciitis with septic shock, caused by *Streptococcus pyogenes*. Tr. 48-49. Dr. Miller explained that *Streptococcus pyogenes* is ubiquitous in the environment and on our skin. Tr. 50. While soft tissue infections like B.R.'s are very rare, they can be fatal. Tr. 51.

Dr. Miller testified that here, there was bacteria on the needle as it penetrated the skin, and the bacteria was deposited into the subcutaneous tissues, or "penetrate[d] a blood vessel," thus getting into the bloodstream. Tr. 111. At the cellular level, Dr. Miller explained that B.R.

[25] For the cases cited in Cook documenting a hematogenous spread of infection, see supra Section III.E.1.b.i.

had "transient bacteremia" and the bacteria that entered the bloodstream from the vaccination seeded the soft tissue of the hip and thigh. Tr. 103, 111. Then, she developed an infection of the bloodstream and septic shock as a final complication. Tr. 103-04. Dr. Miller said that Cook describes this as "metastatic," meaning that it spreads from somewhere else. Tr. 104-05.

In summary, Dr. Miller opined that B.R. was previously healthy, but mildly obese, and was "given a clean bill of health" on the day she received four different injectable vaccinations. Pet. Ex. 43 at 8. Within 15 hours, she had left hip pain and fever. Id. She developed septicemia and septic shock, which caused her death. Id. She was diagnosed with a streptococcal infection. Tr. 97. She had no infection in her throat. Id. There is no evidence that she had evidence of genital infection. Id. She had four needle punctures that violated the skin. Id. Autopsy did not show any source for the bacteria.[26] Pet. Ex. 43 at 8. For all of these reasons, Dr. Miller concluded that bacteria was introduced into the bloodstream by a vaccination, "a rare but reported complication" of vaccination administered by needle injection. Id.; see also Tr. 96-97.

iii. Althen Prong Three

Dr. Miller testified that the onset of B.R.'s illness, the time frame between her vaccinations and thigh pain, was approximately 14 hours. Tr. 69-70. According to Dr. Miller, this time frame was appropriate given his proposed mechanism of causation. Tr. 70. In support of his opinion as to onset, Dr. Miller cites a case described in the Stevens article, where a patient had a fulminant presentation within eight hours of presentation. Id. (citing Resp. Ex. Z, Tab 4 at 2). Dr. Miller opined that 14 hours was a sufficient time for bacteria to enter the bloodstream and seed an infection in the soft tissue and muscle of B.R.'s left hip. Tr. 96-97.

2. Petitioner – Dr. Harry Latham

Petitioner filed four experts reports authored by Dr. Latham. See Pet. Exs. 22-25. Dr. Latham was not called as a witness at the hearing.

In his first report, an affidavit, Dr. Latham provided a summary of B.R.'s medical records. See Pet. Ex. 22 at ¶ 5. He then opined in a conclusory fashion that "there is no evidence to suggest a cause for [B.R.'s] symptoms and disorders other than the vaccinations; and, [B.R.'s] injuries and death five days later were related to the administration of her . . . vaccinations." Pet. Ex. 22 at ¶ 6.

Dr. Latham provided four reasons for his causation opinion in his second report. The first reason was the onset of B.R.'s illness: the time frame between vaccination on March 31, 2009, at about 1:00 PM, and the onset of pain on April 1, at approximately 3:00 AM, indicates a "strong temporal association" which "speaks [to] cause and effect." Pet. Ex. 23 at 1. Second, B.R. received four vaccines, two in each arm. Id. Third, while Dr. Latham acknowledged that the "area affected by necrotizing fasciitis was not at the site of vaccination," he noted that "necrotizing fasciitis has been documented to occur in areas away from the apparent point of

[26] For a more detailed analysis of the facts in the autopsy reports that contribute to Dr. Miller's opinion, see Pet. Ex. 43 at 3-6.

introduction of the bacteria." Id. Fourth, he asserts that bacteria were carried away from the point of introduction (vaccination) to a "possibly more susceptible area which has been traumatized" or has a "compromised blood flow." Id.

In his third expert report, Dr. Latham provided a theory explaining how vaccination in the arm can cause necrotizing fasciitis in the hip. Pet. Ex. 24 at 1-2. Quoting the Merck Manual, he wrote "[i]noculation originates through the skin . . . and the defect may be surgical, trivial, distant from the disease site, or occult." Id. at 1 (quoting Pet. Ex. 26 at 4). He gave examples of the mechanism. The first example is that dental care can cause endocarditis, due to bacteria in the mouth traveling through the blood stream to a compromised heart valve. Id. Another example was sepsis caused by an infection in the bladder or lungs. Id. The third example was lymphohematogenous[27] spread of bacteria "from a distant source such as pneumonia or a remote wound infection." Id. at 2. Dr. Latham stated that *S. pyogenes* is normally found in the skin and can also be harbored in the respiratory tract. Id. With regard to the facts here, he opined that the "injection of the vaccine caused the break in the skin which introduced the pathogenic organism into the bloodstream. This in turn, caused the necrotizing fasciitis." Id. The bacteria "spread rapidly" once it entered the body. Id. It then infected the fascia, "connective bands of tissue that surround muscles, nerves, fat, and blood vessels." Id. Dr. Latham described B.R.'s clinical course and how it was consistent with his proposed theory. Id. at 2-3.

In his third and fourth reports, Dr. Latham addressed respondent's assertions that B.R.'s necrotizing fasciitis was caused from either strep throat or vaginal infection. Pet. Ex. 24 at 3-4; Pet. Ex. 25 at 1-2. Dr. Latham opined that if B.R. had strep throat, she would have had a positive throat culture, and an "inflamed oropharynx." Pet. Ex. 24 at 3; see also Pet. Ex. 25 at 2. He also disagreed that B.R.'s necrotizing fasciitis was caused by vaginal infection since urine cultures did not show streptococcal infection and there was no evidence of vaginal discharge. Pet. Ex. 24 at 3.

3. Respondent – Dr. Sara Vargas, M.D.

a. Background and Qualifications

Dr. Vargas is a doctor licensed to practice in Massachusetts and board-certified in anatomic pathology, clinical pathology, and pediatric pathology. Resp. Ex. A at 1. Dr. Vargas earned her A.B. from Harvard University in 1988 and her M.D. from University of Vermont College of Medicine in 1994. Resp. Ex. AA at 1. She then completed a residency in anatomic and clinical pathology at Brigham and Women's Hospital and a fellowship in pediatric pathology at Children's Hospital. Id. Since completing her residency and fellowship, Dr. Vargas has taught at Harvard Medical School as an Instructor, Assistant Professor, and now Associate Professor and has also worked as a staff pathologist at Children's Hospital and Brigham and Women's Hospital. Id. at 1-2; Resp. Ex. A at 2. Throughout her career, she has served on

[27] Lymph is defined as fluid and cells, primarily lymphocytes, "collected from all parts of the body and returned to the blood via the lymphatic system." Lymph, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28971 (last visited May 27, 2020).

various committees and editorial boards and joined numerous professional societies. Resp. Ex. AA at 3-5. Dr. Vargas has authored or co-authored almost 200 publications. Id. at 17-36.

b. Opinion

i. Althen Prong One

Dr. Vargas does not disagree with Dr. Miller's general theory of causation, but disagrees with his specific opinion that bacteria from a vaccination site can cause necrotizing fasciitis if there is no infection at the vaccination site. Tr. 189-90. Where the source of infection is the skin, Dr. Vargas does not believe that bacteria can proliferate and cause infection if the vaccination site is clean and without infection. Tr. 190. In the alternative, if the source of infection is from another area of the body that is colonized with strep, then an infection at the site is not required for the bacteria to travel to a distant site and cause infection. Tr. 193.

Like Dr. Miller, Dr. Vargas testified that necrotizing fasciitis is "a rapidly moving bacterial infection involving deep soft tissue." Tr. 128. She stated that in approximately fifty percent of cases, the source of the bacteria is not known. Tr. 128, 193-94. The infection that causes necrotizing fasciitis can come from sources other than skin. Tr. 128-29. Strep bacteria "can colonize surfaces that are contiguous with the outside world" like the throat and female genital tract. Tr. 128; see also Resp. Ex. Z at 1-2. Dr. Vargas opined that there can also be hematogenous translocation[28] of strep "from the throat in the presence or absence of symptomatic pharyngitis to a site of blunt trauma or muscle strain." Tr. 130 (quoting Resp. Ex. Z, Tab 2 at 5).[29]

Dr. Vargas agreed that the skin can be the source of bacteria in necrotizing fasciitis. Tr. 130. However, to attribute necrotizing fasciitis to a vaccine given at a distant site, Dr. Vargas feels it would be important to see an infection at the point of entry or site of vaccination. Tr. 130-31. She agreed that vaccinations can introduce bacteria that cause necrotizing fasciitis, but the bacteria can also come from somewhere else because there is no known source in over half of the cases of necrotizing fasciitis. Tr. 133. Dr. Vargas also agreed that bacteria can travel to distant sites. Tr. 135. She testified that bacteria can travel when large amounts of it are seeded in the bloodstream. Id.

In support of her opinion that in order for vaccination to cause a distant site infection, there must first be an infection at the vaccination site, Dr. Vargas referenced the Cook article. Tr. 136-37; Resp. Ex. Z at 3. Dr. Vargas explained that in cases of infectious abscesses post-vaccination, there is a description of an abscess or infection at the site of vaccine injection. Tr.

[28] Dr. Vargas defined translocation as the "way by which bacteria get into the bloodstream." Tr. 188.

[29] Michael E. Pichichero, Complications of Streptococcal Tonsillopharyngitis, UpToDate, https://www.uptodate.com/contents/complications-of-streptococcal-tonsillopharyngitis (last updated Mar. 22, 2019).

138-40; see Resp. Ex. N. at 4-5 tbl.4. Dr. Vargas noted that she was "unable to find a single reference in the medical literature in which any author ever attributed an invasive bacterial infection to vaccination when there was no evident cellulitis occurring at the vaccination site itself."[30] Resp. Ex. Z at 3; see also Tr. 147.

With regard to the necrotizing fasciitis cases summarized by Cook in Table 5, Dr. Vargas did not see "any evidence of any injection site that stayed clean and yet had an infection at a distant site attributed to it." Tr. 144. There was one caveat: Dr. Vargas was unable to read the Thomas article listed in Table 5, and the description of that case study was too ambiguous for her to confirm that there was no infection at the site of vaccination.[31] Tr. 144-45.

In response to the Merck Manual reference cited by petitioner, Dr. Vargas testified that the examples used in that text were cases where an infection had "set up" and then the "infection travel[ed] to a distant site," which is different than a situation where bacteria comes from "a clean site." Tr. 146-47.

Dr. Vargas cited several articles to support her opinions. In an article by Bellapianta, et al.,[32] the authors state, "[n]ecrotizing fasciitis typically follows an injury to the involved site." Resp. Ex. D at 1. The authors also state that "[n]ecrotizing fasciitis has been associated with . . . injection sites." Id. "Although the skin is the most common portal of entry, in 45% of cases, no definitive access point can be found." Id. at 2. One of the risk factors for the illness is obesity, although half of cases occur in healthy persons. Id.

Another article cited by Dr. Vargas was a survey article by Stevens and Baddour.[33] Resp. Ex. F. The authors state that strep "may localize to the exact site of muscle injury due to

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[30] The phrase "invasive infection" was used in an UpToDate article authored by Stevens and Kaplan and filed by respondent as Respondent's Exhibit G. See Dennis L. Stevens & Sheldon L. Kaplan, Group A Streptococcal (Streptococcus Pyogenes) Bacteremia in Children, UpToDate, https://www.uptodate.com/contents/group-a-streptococcal-streptococcus-pyogenes-bacteremia-in-children (last updated June 23, 2012). They define invasive infections to include "bacteremia, pneumonia, osteomyelitis, septic arthritis," necrotizing fasciitis, "or any other infection associated with the isolation of [strep] from a normally sterile body site." Resp. Ex. G at 1.

[31] After the hearing, respondent filed the Thomas article. Resp. Ex. BB. In it, the author states that the patient received a flu vaccine in the left upper arm. Id. at 1. One day later, she developed some discomfort at her vaccination site. Id. Other than the reference to discomfort, there is no description of infection or cellulitis at the site of vaccination. See id. at 1-2.

[32] Joseph M. Bellapianta, Necrotizing Fasciitis, 17 J. Am. Acad. Orthopaedic Surgeons 174 (2009).

[33] Dennis L. Stevens & Larry M. Baddour, Necrotizing Soft Tissue Infections, UpToDate, https://www.uptodate.com/contents/necrotizing-soft-tissue-infections (last updated Feb. 28, 2013).

increased surface expression of the vimentin," a protein, which binds the bacteria. Id. at 2. In cases with no clear entry point, the infection likely occurs due to hematogenous translocation of strep "from the throat (asymptomatic or symptomatic pharyngitis) to a site of blunt trauma or muscle strain." Id. at 3.

On cross-examination, Dr. Vargas agreed that strep can move through the body to remote locations from where it enters. Tr. 174-75. She also agreed that while strep is likely to be found in warm moist areas, it can be found anywhere on the body. Tr. 174. The bacteria "uses multiple tissues, including [] blood, to spread." Tr. 175. Dr. Vargas specifically agreed that a puncture can introduce bacteria into the body. Id.

When questioned about the septic arthritis cases summarized by Cook in Table 7, Dr. Vargas agreed that patients one, two, and four had infections at locations distant from vaccination. Tr. 178-79. She also agreed that Cook did not describe any infection at the site of injection in these three cases. Id. Dr. Vargas stated that the VAERS reports of these three cases were not filed, so there is no additional information about the site of injection.[34] Tr. 193.

Dr. Vargas testified that "septic arthritis is . . . just like necrotizing fasciitis, it presents, and we don't know why. Many, many cases, we say it got there through the bloodstream, but we don't know." Tr. 183. In general, Dr. Vargas, explained that hematogenous is defined as "spread through the bloodstream." Tr. 184. She testified that when there is no evidence of contiguous infection, or direct contamination, "then you have to invoke a hematogenous source." Tr. 183.

ii. Althen Prong Two

Dr. Vargas opined that in B.R.'s case, the bacteria that caused necrotizing fasciitis was introduced by a source other than vaccination. Tr. 168; Resp. Ex. A at 7. She stated that there is "no evidence that [B.R.'s] vaccination site . . . ever showed any evidence of infection" and "there is no known case of necrotizing fasciitis due to a medical injection in which the fasciitis occurred without involving the injected area." Resp. Ex. M at 4. She further opined that "the more common and more probable causes of bacterial seeding of the groin fascia" include strep throat, "direct spread from a nearby genital infection," and unknown or idiopathic. Resp. Ex. A at 8. She states that idiopathic cases are "well-known" but "poorly understood." Id.

In her first expert report, Dr. Vargas opined strep throat was likely. Resp. Ex. A at 7. In her supplemental expert report, Dr. Vargas agreed with the testimony by Dr. Mills, when he "pointed to the throat as one of the possible sources of bacterial seeding." Resp. Ex. M at 2. At

[34] Respondent cited an article by Varricchio et al., which explains that "VAERS are not formal case reports, but rather nonstandardized descriptions of symptoms and signs temporally associated with a vaccination or vaccinations. The information in a report is not necessarily complete, nor is it verified in most cases." Frederick Varricchio et al., Understanding Vaccine Safety Information from the Vaccine Adverse Event Reporting System, 23 Pediatric Infectious Disease J. 287, 288 (2004) (filed as Resp. Ex. R).

the hearing, Dr. Vargas testified that the medical records state that B.R. had a sore throat and "mildly injected" throat, which supports her opinion that the strep bacteria could have come from the throat. Tr. 154-57. Dr. Vargas asserts that B.R.'s sore throat had occurred "off and on for a week" prior to her transfer to Phoebe Putney on April 3, and thus, it preceded her vaccination. Resp. Ex. Z at 2.

According to Dr. Vargas, B.R.'s negative rapid strep test and negative throat culture do not "rule out" the possibility of *S. pyogenes* in the throat. Resp. Ex. M at 5. She notes that "throat cultures are known to miss 5-10% of *S. pyogenes* infection[s]." Id. When asked about the accuracy of the rapid strep test and throat culture, Dr. Vargas agreed with Dr. Miller's testimony that the tests were 90% accurate, stating Dr. Miller was "not too far off." Tr. 171. Respondent filed a medical article by Wald[35] which confirmed the veracity of Dr. Miller's opinion. Resp. Ex. M, Tab 7 at 5. Wald observes that "[w]hen performed properly, the sensitivity of [a] throat culture is 90 to 95 percent for [group A strep]." Id.

The reference in B.R.'s medical record to a rash was significant to Dr. Vargas. She testified that "a rash is a common manifestation of strep pyogenes infection." Tr. 156. She noted the records indicate on April 4 that a rash had been present off and on for three days. Resp. Ex. Z at 3 (citing Pet. Ex. 14 at 28, 59). Dr. Vargas opined that rashes in patients with strep throat are often seen one to two days after the onset of bacterial infection. Id. She stated that "[t]he characteristic rash occurring in the setting of group A strep infection is termed scarlet fever." Id. She further opined that in patients with scarlet fever, the most common site for bloodstream infection (sepsis) is the pharynx (throat). Id.

On cross-examination, Dr. Vargas was questioned about B.R.'s medical record entries related to the presence of a rash on physical examination. On March 31 and April 1, no rash was noted on examination. Pet. Ex. 14 at 3-4, 10-12. On April 3, Dr. Kocherla noted a rash on B.R.'s neck. Pet. Ex. 13 at 17; Resp. Ex. X at 40. Dr. Vargas agreed that if the infection started in B.R.'s leg on April 1, then one could attribute a rash present on April 2 or 3 to the infection in B.R.'s leg. Tr. 174.

Next, Dr. Vargas testified about the autopsy, specifically her review of one microscopic slide of lung tissue. She opined that lung tissue slide Q showed inflammatory cells and intra alveolar macrophages. Tr. 160-63. Dr. Vargas described an area with "mucopurulent material in alveolar spaces." Tr. 163. She explained that these findings indicated "possible early bronchopneumonia." Resp. Ex. M at 2; see also Resp. Ex. Z at 3-4. Dr. Vargas stated these findings "fit[] very well with bacteria coming down from the upper respiratory tract, down into the lungs." Tr. 164. However, she explained that it "doesn't have to be strep" that caused the finding seen in the lung slide; "[o]ther bacteria could have done this, but it fits, you know, that it could have been strep." Id. Dr. Vargas conceded that the finding on the lung slide was not unique to, or diagnostic of, strep throat. Tr. 185.

[35] Ellen R. Wald, Approach to Diagnosis of Acute Infectious Pharyngitis in Children and Adolescents, UpToDate, http://www.uptodate.com/contents/approach-to-diagnosis-of-acute-infectious-pharyngitis-inchildren-and-adolescents (last updated June 2, 2015).

More importantly, Dr. Vargas conceded that the findings were "very common in any death, any hospital death that [she] see[s]." Tr. 185. Dr. Vargas testified that it is common for patients to get pneumonia when they are very ill. Id. Further, she stated that when patients get septic, it is "common to start getting the proteinaceous exudate into the lung. It's the lung's way of reacting." Id.

In addition to the lung tissue slide, Dr. Vargas believes that B.R.'s chest X-ray[36] showed "opacities in the lung fields," that looked like "very early bronchopneumonia." Tr. 165. She testified that there was no "frank" or "obvious pneumonia" but they could not "exclude bronchitis or an atypical pneumonia." Tr. 188. Based on the chest X-ray, Dr. Vargas believes the changes she saw in lung tissue occurred before B.R. became critically ill. Tr. 186. She explained that portable chest X-rays, like the one here, are more difficult to interpret than standard chest X-rays with two views. Tr. 188. Dr. Vargas said that the radiologist saw a "slight prominence of the interstitial markings in the infrahilar regions," which she interpreted as "bronchitis and an early bronchopneumonia." Tr. 187. However, the radiologist who interpreted B.R.'s portable chest X-ray stated, "No evidence of frank pneumonia. Cannot exclude bronchitis or atypical pneumonia." Pet. Ex. 13 at 27. The radiologist did not diagnosis B.R. with bronchitis or early bronchopneumonia. See id.

Dr. Vargas filed a several articles that specifically support her opinion that the source of B.R.'s strep infection was the throat, including the Stevens and Baddour article. See Resp. Ex. F. The authors state that "[i]n cases with no clear portal of entry, the pathogenesis of infection likely consists of hematogenous translocation of [Group A *Streptococcus*] from the throat . . . to a site of blunt trauma or muscle strain." Id. at 3.

In the UpToDate article by Stevens and Kaplan, the authors agreed that "among patients with scarlet fever, the pharynx is the most common source of bloodstream [Group A *Streptococcus*]." Resp. Ex. G at 3. However, they noted that "[t]he least common source of bacteremia in children has been the lower respiratory tract. When bacteremic [Group A *Streptococcal*] pneumonia occurs, it usually is associated with prior viral infections, particularly influenza." Id. They also state that "[t]he most frequent source of [Group A *Streptococcal*] bacteremia in children is the skin," incited by cellulitis, minor trauma, and varicella infections. Id. at 2.

iii. Althen Prong Three

Dr. Vargas testified that a 14 hour onset seemed too short a period of time for transient bacteremia to occur from a vaccine injection, and for the bacteria to travel to a distant site and multiply. Tr. 190-91. Dr. Vargas opined that onset would not "be less than 24 hours." Tr. 190. She did not cite any source to support her onset opinion.

Respondent filed several articles addressing onset. In Stevens, the authors studied 20 cases of Group A *Streptococcal* soft tissue infection. Resp. Ex. Z, Tab 4 at 2. One patient had

[36] Dr. Vargas testified that she did not review the actual chest X-ray, only the report. Tr. 186.

"fulminant myositis eight hours after presentation." Id. In Thapa et al.,[37] the authors presented a case report of an infant who developed necrotizing fasciitis following a BCG[38] vaccination. Resp. Ex. H at 1. The infant had symptoms of infection 18 hours after vaccination. Id.

The authors of Thuong, et al.[39] summarize data of nine children who developed severe *Staphylococcus aureus* infections following vaccination.[40] Resp. Ex. O at. 1. Three children had a systemic syndrome consistent with toxic shock syndrome. Id. at 2. Four of the children had skin and soft tissue infections, including one with necrotizing fasciitis. Id. All of the skin and soft tissue infections occurred at the vaccination site. Id. In seven of the nine children, onset of symptoms occurred in a range of nine to 14 hours. Id. at 3.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that

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[37] Rajoo Thapa et al., Necrotizing Fasciitis Following BCG Vaccination, 48 Indian Pediatrics 235 (2011).

[38] BCG stands for "Bacille-Calmette-Guérin." Resp. Ex. H at 1. BCG is a vaccine for tuberculosis. Tuberculosis (TB): BCG Vaccine Fact Sheet, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/tb/publications/factsheets/prevention/bcg.htm (last reviewed May 4, 2016).

[39] Tang Chi Thuong et al., An Outbreak of Severe Infections with Community-Acquired MRSA Carrying the Panton-Valentine Leukocidin Following Vaccination, 2 PLoS ONE e822 (2007).

[40] The vaccines included Hepatitis B ("HBV"), Measles, Mumps, Rubella ("MMR"), and varicella. Resp. Ex. O at 3.

the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Human Servs., No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Human Servs., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Human Servs., No. 03–1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Human Servs., No. 90–1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Human Servs., No. 90–1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that B.R. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that B.R. suffered an injury that was actually caused by a

vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that B.R. suffered a Table Injury, she must prove that a vaccine B.R. received caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and B.R.'s injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for B.R.'s injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and B.R.'s injury ("Althen Prong Three"). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

"Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred." LaCour v. Sec'y of Health & Human Servs., No. 90–316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); accord Burns v. Sec'y of Health & Human Servs., No. 90–953V, 1992 WL 365410, at *6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff'd, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec'y of Health & Human Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Id.; see also De Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008).

D. Causation Analysis

1. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451

F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Petitioner cannot prevail with just an opinion that since there is no other factor to explain B.R.'s infection but the vaccines, the vaccines must have been the cause. However, this case involves more than that assertion. Both Dr. Miller and Dr. Vargas, as well as Cook and other authors of the medical literature filed in this matter, agree that there is streptococcal bacteria on the skin. They agree that an injection can serve as a portal of entry for the bacteria to enter the tissues and blood stream. They agree that this mechanism of action—hematogenous spread through the blood stream—can cause sepsis and other rare, adverse, and even fatal, infections. They agree that these invasive infections can occur in sites distant to the portal of entry. For example, in osteomyelitis, the infection occurs in the bone. In septic arthritis, the infection occurs in the joint. In the case of endophthalmitis, the infection occurs in the eye. This causal mechanism, recognized by the experts and authors of relevant medical literature, is thus, sound and reliable.

Respondent, however, adds an additional requirement to the causal mechanism as it relates to the facts and circumstances presented here. Respondent argues that a patient must have an infection at the portal of entry—here, the site of vaccination—in order for there to be spread of that bacteria by the bloodstream to a remote site. None of the medical articles filed by either party address that narrow issue. The articles provide a brief summary of the facts about each case report. Some of the articles describe the local condition of the skin where the portal of entry is the skin. The take away from the medical literature relevant here is that injections, including vaccinations given by injection penetrating the skin, can provide a portal of entry for bacteria to spread via the bloodstream to other sites.

Dr. Vargas agreed that the mechanism of hematogenous spread is the same for septic arthritis as it is for necrotizing fasciitis. Likewise, Cook did not draw distinctions in the mechanism of hematogenous bacterial spread, as applied to septic arthritis, osteomyelitis, or necrotizing fasciitis. Certainly, the case reports specific to necrotizing fasciitis occurring after vaccination may have included information suggesting there may have been signs of infection at the site of vaccination or injection. However, this was not universal. Further, the case reports of invasive infections caused by strep bacteria, including bacteremia, osteomyelitis, and septic arthritis, often omitted a description of the vaccine or infection site. None of the authors of the relevant articles stated an opinion like that held by Dr. Vargas, specifically that there must be

infection at the vaccine site for a remote infection to occur. Thus, it would be erroneous for the undersigned to impose the equivalent of a "condition precedent" to a causal mechanism where physicians who have studied and authored medical reports on the subject did not do so. Accordingly, the undersigned finds that petitioner has set forth a sound and reliable medical theory, satisfying Althen Prong One.

2. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

Petitioner has demonstrated that administration of vaccines can lead to remote site infections, including necrotizing fasciitis and septic shock, through hematogenous spread of bacteria and thus, satisfied Althen Prong One. Petitioner has also shown causation specific to this case—that B.R.'s vaccinations lead to her necrotizing fasciitis and septic shock, consequently causing her death. There is preponderant evidence to establish a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278).

There are three reasons for this finding. First, B.R.'s clinical course and autopsy are consistent with the mechanism proposed by Dr. Miller. Second, there is insufficient evidence to support a finding that B.R. had strep throat, early pneumonia, or a urogenital source of infection. And third, this finding is consistent with the medical records and testimony of treating physicians, Dr. Kocherla and Dr. Darden, and pathologist, Dr. Latham.

a. Clinical Course and Autopsy

B.R. was healthy, although mildly obese, on the day that she received four vaccinations by injection—four needle punctures of the skin. Within 15 hours, she had left hip pain and fever. A throat culture was negative for strep, but a blood culture revealed strep in her blood. She

developed septicemia and septic shock, which caused her death. There is no evidence that she had a genital infection. The autopsies did not show any source for the bacteria. For these reasons, Dr. Miller concluded that bacteria was introduced into the bloodstream by a vaccination, "a rare but reported complication" of vaccination administered by needle injection. Pet. Ex. 43 at 8; see also Tr. 96-97.

Through the expert report and testimony of Dr. Miller, petitioner established by preponderant evidence that B.R. developed transient bacteremia—that is, bacteria entered the bloodstream from vaccination, which seeded the soft tissue of the hip and thigh. The autopsy established that B.R. had *S. pyogenes*, a bacteria known to be present on the skin and a known cause of infection. The autopsy findings were consistent with septic shock and an infection in tissue of the left thigh and hip. B.R. developed necrotizing fasciitis, infection of the bloodstream, and septic shock which caused her death.

Moreover, B.R.'s clinical course was consistent with the case reports in the medical literature filed in this case. In Stevens, the authors studied 20 cases of Group A *Streptococcal* soft tissue infection. Resp. Ex. Z, Tab 4 at 1. Abrupt onset with severe pain was the common presentation. Id. at 2. One patient had "fulminant myositis eight hours after presentation." Id. In addition to onset, the clinical course of several of the patients was similar in time frame to B.R.'s course. Twelve of the 20 patients had bacteremia, and of these patients, six died. Id. at 4. Of these six, three died within 36 hours of hospital admission. Id. Nineteen patients had shock on admission to the hospital or shortly thereafter. Id.

b. B.R. Did Not Have Strep Throat, Pneumonia, or a Urogenital Source of Infection

Based on the medical records, results of the throat culture, autopsies, expert reports and testimony, and the totality of facts and circumstances, the undersigned finds that B.R. did not have strep throat, pneumonia, or a urogenital source of infection that caused her necrotizing fasciitis and septic shock.

While the records include a reference to sore throat and a description that B.R.'s throat was "mildly injected," this evidence is insufficient to establish that B.R. had strep throat given the weight of the evidence against such a finding. The most compelling evidence was B.R.'s negative throat culture. When performed properly, the literature and experts agreed that this test has an accuracy rate of 90-95%. See Tr. 32, 71, 171. There is no evidence that B.R.'s throat culture was performed improperly. The negative results establish that it is very unlikely that she had strep throat or that the bacteria that seeded her necrotizing fasciitis came from the throat.

The consecutive physical examinations of B.R. conducted by different doctors over a five-day period provide more evidence that B.R. did not have strep throat. The physicians who performed these exams did not document evidence of the usual characteristics of strep throat, which include inflamed appearance, often with white follicles or exudate. B.R. did not have adenopathy or enlarged lymph nodes in the neck area suggestive of a throat infection. None of B.R.'s treating physicians diagnosed her with strep throat. Additionally, the two pathologists who performed autopsies did not attribute her infection to strep throat.

There is also insufficient evidence to support respondent's position that B.R. may have had early pneumonia or bronchopneumonia. There is no documentation that B.R. had a cough, wheezing, or respiratory distress, and until she became critically ill on April 4, she had no respiratory distress. Medical records establish that on her admission to Phoebe Putney on April 3, B.R. had no history of cough, wheezing, trouble breathing, or respiratory distress. Lung sounds were clear bilaterally. B.R. was not diagnosed with pneumonia by any of the doctors who examined her on March 31, April 1, April 3, or April 4. The two pathologists who performed autopsies also did not diagnose pneumonia.

Dr. Vargas opined that one lung tissue slide (slide Q) may have shown findings that indicated "possible early bronchopneumonia." Resp. Ex. M at 2; see also Resp. Ex. Z at 3-4. However, opinions based on possibilities are insufficient to establish causation. See, e.g., Moberly, 592 F.3d at 1322; De Bazan, 539 F.3d at 1351; Burns, 1992 WL 365410, at *6; LaCour, 1991 WL 66579, at *5.

Further, Dr. Vargas conceded that the findings on lung slide Q, are "very common in . . . any hospital death," as it is common for patients to get pneumonia where they are very ill. Tr. 185. Assuming this was true for B.R., if she did have pneumonia, it would have occurred after she became very ill on April 4, and therefore, it would not have caused the infection that manifested as hip pain on April 1.

With regard to Dr. Vargas' opinion that B.R.'s chest X-ray showed very early bronchopneumonia, that opinion was based, in part, on her review and opinion of one lung slide. For the reasons explained above, the undersigned does not find Dr. Vargas' opinion about the lung slide to be persuasive evidence that B.R.'s infection was caused by pneumonia. Moreover, the undersigned finds the opinion of the interpreting radiologist to be the most reliable evidence as to the results of the X-ray, and that opinion did not include the finding of pneumonia.

Lastly, there is no evidence to support a conclusion that B.R.'s infection originated from a urogenital source. The medical records do not document that B.R. ever complained of urogenital symptoms. Her urinalysis was normal. Her urine culture did not show bacterial infection. B.R. was not diagnosed with urogenital infection by any treating physician. On autopsy, external genitalia was unremarkable and there was no inguinal lymphadenopathy. The pathologists did not make any findings consistent with urogenital infection, or attribute B.R.'s infection to a urogenital source.

In summary, there is either no evidence or insufficient evidence to show that the source of B.R.'s infection was due to any source other than her vaccinations. As to Dr. Vargas' position that the cause was idiopathic or unknown, that might be a viable option but for the fact that B.R. had four injections of her skin, and the breach of the skin, even when the skin is properly cleaned, is known to be associated with remote infections, caused by hematogenous spread. The undersigned cannot ignore the fact of B.R.'s vaccinations, and the resulting portal of entry that each injection created, so as to entertain a suggestion that they did not play a role, and thus conclude that the cause here was idiopathic.

c. Treating Physicians[41]

Several of B.R.'s treating physicians records offered evidence supportive of vaccine causation. On April 3, Dr. Kocherla's diagnosis was post-vaccination reaction. He ordered a sepsis workup, including blood cultures that revealed *S. pyogenes*. In his deposition, Dr. Kocherla testified that he believed that B.R. had sepsis or post-vaccination myopathy, and he was correct. The blood cultures revealed that B.R. had *S. pyogenes* sepsis.

Orthopedist Dr. Darden examined B.R. after her transfer to Phoebe Putney. His impression was transient synovitis secondary to viral load from vaccines and possible bacterial sepsis of the joint. Testing of the joint was not performed, so it is not known whether B.R. had a septic joint. Regardless, based on the literature filed in this case, a septic joint caused by bacteria occurs due to the same mechanism of action propounded by Dr. Miller.

The pathologists were split on the issue of vaccine causation. In his autopsy, Dr. Burns did not express an opinion as to vaccine causation, but in his deposition, he testified that B.R.'s vaccinations had nothing to do with her illness. On the other hand, Dr. Latham opined that the vaccines may have caused B.R.'s illness based on the fact that she had *S. pyogenes*, which is known to be present on the body, and that the illness can be caused by a skin prick, or in this case vaccination.

On the whole, the undersigned finds the records and opinions of Drs. Kocherla, Darden, and Latham provide support for vaccine causation, and when combined with the other evidence summarized above, add to the weight of the evidence in favor of petitioner.

The undersigned found petitioner's Althen Prong One theory sound and reliable, and now finds petitioner, by preponderant evidence, has shown that the vaccinations were the source of the bacteria that caused B. R.'s infection and death. Accordingly, petitioner has satisfied Althen Prong Two.

3. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." De Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Human Servs., 773 F.3d 1239, 1243

[41] The undersigned has considered the opinions and testimony of all of the physicians whose depositions were filed in this matter but gives more weight to the opinions and testimony of those who treated B.R. and created contemporaneous medical records. Thus, the opinion of Dr. Mills, who was not a treating physician nor an expert in this matter, was afforded less weight.

(Fed. Cir. 2014); Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

The undersigned finds petitioner has provided preponderant evidence of a proximate temporal relationship between B.R.'s vaccinations and the first manifestation of the infection which led to her death. Dr. Miller and Dr. Vargas agree that the time frame between B.R.'s vaccinations and the onset of her infection, marked by hip and thigh pain, was approximately 14 hours. Dr. Miller opined that 14 hours was appropriate, and cited to the case report published by Stevens. Dr. Vargas testified that 14 hours seemed too short, but did not cite any literature or other evidence to support her testimony on this point. The articles cited by respondent provided eight cases where onset was in the range of nine to 18 hours. See Resp. Ex. H at 1 (discussing patient with symptoms of infection 18 hours post-vaccination); Resp. Ex. O at 3 (describing seven children who had onset ranging from nine to 14 hours). Given the case reports described in the literature, and the lack of other evidence, the undersigned finds the petitioner's evidence as to onset more credible and persuasive.

E. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence "that [B.R.'s] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Human Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen Prong Two, the undersigned found the respondent failed to establish evidence to show that B.R.'s infection was caused by a source other than her vaccinations. Thus, respondent did not prove by a preponderance of evidence that B.R.'s injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

V. CONCLUSION

This is a very tragic case. The undersigned extends her sympathy to the petitioner and family of B.R. for their loss. The undersigned's decision, however, is not based on sympathy, but based on the evidence. For the reasons discussed above, the undersigned finds that petitioner has established by preponderant evidence that she is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master